CONSENT FORM

Title of Research: Unlocking Dystonia from Parkinson's Disease with Directional DBS Technology

UAB IRB Protocol #: IRB-300001136

Principal Investigator: Harrison Walker, MD

Sponsor: The Michael J. Fox Foundation for Parkinson's Research (MJFF)

Purpose of the Research

We are asking you to participate in a research study because you are already enrolled in the BRAIN Initiative study and have been diagnosed with Parkinson's disease with dystonia. The purpose of this research study is to measure brain rhythms from new directional deep brain stimulation (DBS) lead technology to better understand and treat dystonia associated with Parkinson's disease (PD).

Dystonia is a twisting involuntary movement that is present in some patients with PD. Dystonia can improve with medications and with DBS. New directional lead designs used in the Brain Initiative study which include 8 rather than 4 contacts, allow flexibility to better treat dystonia and other resistant symptoms in the legs versus conventional DBS.

In this study, we will contrast brain activity in PD patients with and without dystonia with recordings from the DBS lead and the surface of the brain using electrodes that will already be in place for the Brain Initiative study. We will then determine if these brain rhythms predict stimulator settings to better treat "off" dystonia and other resistant motor symptoms from PD. We will enroll 10 participants with dystonia and compare their brain rhythms with 20 participants without dystonia.

Explanation of Procedures

This study occurs during two visits that are already scheduled as part of the BRAIN Initiative study. We will administer one additional rating scale to assess the severity of dystonia. This additional procedure will add no more than 5 minutes to your BRAIN Initiative study visits at baseline, 2, 4, 6, and 12 months after surgery.

After surgery and at the time of your BRAIN initiative visit in which we activate the contact segments on the directional DBS lead, we will measure how well DBS improves dystonia and other motor symptoms versus your level of dystonia prior to surgery using the same scale administered during the first study visit.

If you agree to participate in this study, we will review and collect information from your electronic medical record at UAB as well as collect data from your participation in the BRAIN Initiative study.

Risks and Discomforts

Participation in this research carries a small risk of loss of confidentiality. We will code the information we collect from you rather than use your name or other information that can directly identify you. We will make every effort to maintain your confidential information and protect personal information obtained for the study.

We will administer the dystonia rating scale, along with a series of other tests for the BRAIN Initiative study. All of these tests will take some time to complete and may result in some fatigue.

Benefits

You may not benefit directly from taking part in this study. Even if you do not benefit from this study, the knowledge gained may eventually help us to better optimize surgical targeting and to develop better stimulation strategies, based on a deeper understanding of how DBS alters the function of brain circuits in people with Parkinson's disease.

Alternatives

The alternative is not to participate in this study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the MJFF, and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.

If you choose to participate in this study, you agree that your de-identified clinical data may be shared with The Michael J. Fox Foundation for Parkinson's Research (the study sponsor). This data may be kept for storage at a central repository either hosted by The Michael J. Fox Foundation, its collaborators, or consultants and will be kept indefinitely. In order to advance scientific discoveries, your de-identified data will be made publically available (with no personal identifying information) for the intended use of research in Parkinson's disease as well as other biomedical research studies that may not be related to Parkinson's disease.

Your consent form will be placed in your medical record at UAB Health System. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigators.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e.

laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities so that the costs for clinical services can be appropriately paid for by either the study account or by the patient/patient's insurance.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation in Research

You will be paid $35 per study visit for your participation in this study following the completion of the study visits at baseline, 2, 4, 6, and 12 months.

If you quit the study, you will be paid $35 for each study visit up to that point. Payments will be

made by check or direct deposit within 4 weeks of completion of each study visit. If you complete all visits, you will be paid up to $175.

Reimbursement for travel expenses may be provided on a case-by-case basis and should be discussed with study personnel in advance if needed.

Significant New Findings

Occasionally significant new findings develop during the course of a study that may relate to your willingness to continue participation. You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Harrison Walker. He will be glad to answer any of your questions. Dr. Walker's number is 205-934-0683. Dr. Walker may also be reached after hours by paging him at 205-934-3411 (beeper 9539).

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
UAB IRB Protocol Number: IRB-300001136
Research Protocol: Unlocking Dystonia from Parkinson's Disease with Directional DBS Technology
Principal Investigators: Harrison Walker, M.D
Sponsor: Michael J. Fox Foundation for Parkinson's Research

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____